UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA,	:	S1 18Cr0006 (DLC)
-v-	:	OPINION AND ORDER
ERNESTO LOPEZ and AUDRA BAKER, Defendants.	:	

Appearances:

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DENISE COTE, District Judge:

Defendant Ernesto Lopez was found guilty on February 21, 2019, following an eight-day jury trial, on eight counts of distributing a controlled substance and one count of conspiring to distribute or possess with intent to distribute a controlled substance.[1] Defendant Lopez is a medical doctor who, from 2015 through October 2017, operated several pain management medical

[1] Co-defendant Audra Baker was acquitted on all counts.

practices in Manhattan, Queens, and Long Island. Through that practice he distributed vast quantities of oxycodone and fentanyl. This Opinion describes rulings issued by the Court regarding the admissibility of testimony presented by the defendant's expert Dr. Carol Warfield of Harvard Medical School.

Background

The evidence at trial included proof of the following. Lopez, who had no specialized training or experience with pain management, retired from the Veterans' Administration and shortly thereafter, in 2015, set up a pain management practice. He gave little or no treatment to his patients other than prescribing opioids to them month after month.

Lopez, had written only 43 controlled substance prescriptions in 2014. In 2015, he wrote 5,168; in 2016, 7,690; in 2017, 5,679.[2] Between January 2015 and October 2017, Lopez issued a total of 11,926 prescriptions for oxycodone and 2,375 fentanyl prescriptions.

Patients visiting the Lopez offices would pay $200 to $300 in cash per visit. In advance of their first visit, office staff informed new patients that they must bring copies of their medical records, the results of a Magnetic Resonance Imaging

[2] Lopez's operation of his pain clinics ceased in the Fall of 2017, after his arrest on November 2, 2017.

(MRI) scan, the results of a urine analysis, and a photograph of a secure place where they intended to keep any prescribed medication. Upon arriving at the medical office, the patient would fill out a questionnaire, indicating, inter alia, their current level of pain on and off medication, whether they felt an improvement in pain since their last medical visit, and identifying their complained-of injuries.

As testimony and undercover recordings showed, when Lopez met with patients, he reviewed the patient's records, asked the patient whether they had previously been prescribed pain medication, and sometimes conducted a cursory physical examination of the patient. Lopez then issued patients prescriptions for oxycodone and/or fentanyl. Lopez gave regular patients these prescriptions each month they came for their appointments. Lopez typically maintained or increased a patient's dosage of oxycodone and/or fentanyl, regardless of a returning patient's reported pain levels. For instance, even if the reported pain levels were the same with or without the medication, or were relatively low, Lopez would prescribe the same or a greater amount of the opioids. At times, Lopez handed patients with whom he was particularly close loose oxycodone pills between their monthly visits.

Patients were periodically required to present urine test results to the clinic. Lopez continued to prescribe oxycodone

to the patients even if the test results showed no evidence that the person was using the oxycodone, and even if the results showed that the person was actively using illegal drugs such as cocaine.

Lopez also prescribed Subsys -- a powerful fentanyl spray indicated for breakthrough cancer pain -- to patients with no diagnosis of cancer or cancer-related pain. Lopez arranged to send large quantities of Subsys to one patient's home through a mail order distribution system when the patient had no need for the drug and no notice that it would be coming to his home. Lopez also tried to become a speaker for Insys, the maker of Subsys, which would have been a very lucrative position. Lopez applied to become a speaker in April 2015. In that month, Lopez issued 16 prescriptions for Subsys, almost double what he had issued the month prior and around five times the number he issued the following month.

The witnesses at trial included former patients who were addicted to oxycodone and/or fentanyl while under Lopez's treatment. Some of the witnesses were in the business of selling some or all of the opioids they received from Lopez.

One witness was a young woman who had performed office work at one of his pain management practices. Lopez treated her for scoliosis and arthritis. Then, he asked her to help him get oxycodone pills by filling an oxycodone prescription he issued

to her and giving him the pills. When it came time for her urine test, Lopez gave her an oxycodone tablet, instructed her to crush it and add it to her urine during the urine test, and drove her to the laboratory for the urine test.

No evidence was presented at trial that Lopez provided any medical care between 2015 and October 2017 to the patients to whom he gave opioid prescriptions other than prescribing opioids and some muscle relaxants and anti-anxiety medication. No evidence was presented showing that he referred these patients for other medical care, including surgery or physical therapy.

Pursuant to federal regulations, a physician may lawfully distribute a controlled substance by issuing a prescription, but only "for a legitimate medical purpose" while "acting in the usual course of his professional practice." 21 C.F.R. § 1306.04. At trial, the Government had the burden of proving beyond a reasonable doubt that Lopez prescribed oxycodone and/or fentanyl "other than for a legitimate medical purpose, other than in good faith, and not in the usual course of medical practice." United States v. Wexler, 522 F.3d 194, 206 (2d Cir. 2008). A doctor acts in "good faith" if he acts in the "honest exercise of [his] best professional judgment as to a patient's medical needs" and in accordance with what he "reasonably believed to be proper medical practice." Id. at 205. Whether a doctor acted in good faith is assessed based on a standard of

objective reasonableness. United States v. Vamos, 797 F.2d 1146, 1153 (2d Cir. 1986). A doctor may not substitute his own views of what is good medical practice for standards generally recognized and accepted in the United States. Thus, the standard of care applicable to doctors engaged in the practice of pain management may be relevant to a jury's evaluation of whether a doctor's conduct "deviated so far from the usual course of professional practice that his actions become criminal." Wexler, 522 F.3d at 204 (citation omitted).

Both the Government and Lopez called expert witnesses during the trial. The Government called Dr. Seth Waldman, an expert in the field of pain management and practicing physician at the Hospital for Special Surgery. Dr. Warfield testified as an expert witness on behalf of Lopez. Dr. Warfield currently serves as a professor of Anesthesia at Harvard Medical School, where she teaches pain medicine. Dr. Warfield practiced from 1980 to 2013 as an anesthetist and pain management physician at the Beth Israel Deaconess Medical Center in Boston. Dr. Warfield has published numerous articles on pain management and edited several major textbooks on the subject. She testified at trial that Harvard's pain clinic at Beth Israel Deaconess Medical Center is named after her.

On January 11, 2019, Lopez and the Government exchanged initial expert disclosures, pursuant to Rule 16, Fed. R. Crim.

P. On January 28, the Government provided a six-page supplemental Rule 16 disclosure of Dr. Waldman's testimony (the "January 28 Disclosure"). The January 28 Disclosure included a detailed description of standard medical practices in pain management, a description of the proper use of oxycodone to address pain as well as the dangers associated with this medication and precautions that physicians should consider when prescribing it, and a shorter description of the standard for prescribing fentanyl and fentanyl's dangers. The January 28 Disclosure also stated that Dr. Waldman was expected to opine, based on the examination of certain identified patient files, that some of the opioid prescriptions reflected in those files were issued outside the usual course of professional practice.

On February 7, Lopez provided the Government with a roughly three-page supplemental Rule 16 disclosure (the "February 7 Disclosure").[3] The February 7 Disclosure did not include a description of the standard of care that applies to a pain management practice or the prescribing of opioids or identify any specific disagreements that Dr. Warfield had with the January 28 Disclosure. Instead, it explained that Dr. Warfield would make three essential points during her testimony. First, she would explain that there is a "fierce debate" within the

[3] This disclosure was dated February 8, but submitted on February 7.

medical arena about the best practices in many areas of pain management, that “there remains a lack of consensus” on these issues, and that “no specific regulations or requirements of pain management doctors exist” as to many pain management practices, including how to deal with patients with histories of substance abuse. Second, she would explain the terms “best practices,” “standard of care,” and “the usual course of medical practice,” noting that the term “standard of care” is used in civil litigation -- primarily medical malpractice cases -- and emphasizing that pain management doctors retain discretion on how to manage treatment of pain. Finally, she would testify, based on a review of identified patient files, that “in general” Dr. Lopez was acting within the usual course of professional practice in his treatment of chronic pain, including his prescribing of opioids. To the extent that his records indicate "conduct below certain levels of standard of care", she would explain that the conduct remained "within the broader range of the medical professional engaged in the usual course of professional practice." The disclosure explained that this opinion would be based on eight factors, such as the establishment of a relationship with the patient, taking a general medical history, conducting toxicology tests, and obtaining patient responsibility agreements for opioid based treatments.

In a February 7 letter, the Government moved to preclude Dr. Warfield's proposed testimony. The Government's objections were both general and discrete. It objected to the entire February 7 Disclosure as providing inadequate notice of Dr. Warfield's expected testimony. With regard to topics that the February 7 Disclosure described, it objected to Dr. Warfield providing legal standards, explaining what the law is or should be, and defining terms such as "usual course of professional practice," "standard of care," or "negligence." It also objected to, and Lopez then withdrew, proposed testimony to the effect that Lopez did not act as a criminal. This Opinion describes the Court's February 11 ruling on this February 7 motion as well as subsequent rulings on objections to testimony presented by Dr. Warfield during the trial.

Discussion

The general standards for the admission of expert testimony are well established. Federal Rule of Evidence 702 governs the admissibility of expert testimony. It provides:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
>
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;

(b) the testimony is based on sufficient facts or data;

(c) the testimony is the product of reliable principles and methods; and

(d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702.

The proponent of expert testimony carries the burden of establishing its admissibility by a preponderance of the evidence. United States v. Williams, 506 F.3d 151, 160 (2d Cir. 2007). Expert testimony admitted under Rule 702 must be relevant and rest on a reliable foundation. Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 597 (1993); Williams, 506 F.3d at 160. An expert's opinion is relevant if it will "help the trier of fact to understand the evidence or to determine a fact in issue." Fed. R. Evid. 702; see Daubert, 509 U.S. at 591.

"Even after determining that a witness is 'qualified as an expert' to testify as to a particular matter, Fed. R. Evid. 702, and that the opinion is based upon reliable data and methodology, Rule 702 requires the district court to make a third inquiry: whether the expert's testimony (as to a particular matter) will 'assist the trier of fact.'" Nimely v. City of New York, 414 F.3d 381, 397 (2d Cir. 2005). Expert testimony assists the trier of fact "when it sheds light on

activities not within the common knowledge of the average juror." Wexler, 522 F.3d at 204 (citation omitted).

"[E]xpert testimony is not admissible under Federal Rule of Evidence 702 if it usurps the role of the jury in applying the law to the facts before it, as such testimony undertakes to tell the jury what result to reach, and thus attempts to substitute the expert's judgment for the jury's." Callahan v. Wilson, 863 F.3d 144, 153 (2d Cir. 2017), cert. denied, 138 S. Ct. 1261 (2018)(citation omitted). "Fed. R. Evid. 704 was not intended to allow experts to offer opinions embodying legal conclusions." United States v. Stewart, 433 F.3d 273, 311 (2d Cir. 2006) (citation omitted). As such, "an opinion that purports to explain the law to the jury trespasses on the trial judge's exclusive territory." Id. "[A]lthough an expert may opine on an issue of fact within the jury's province, he may not give testimony stating ultimate legal conclusions based on those facts." United States v. Bilzerian, 926 F.2d 1285, 1294 (2d Cir. 1991). "Even if a jury were not misled into adopting outright a legal conclusion proffered by an expert witness, the testimony would remain objectionable by communicating a legal standard -- explicit or implicit -- to the jury." Hygh v. Jacobs, 961 F.2d 359, 364 (2d Cir. 1992). The Second Circuit has found, for example, that expert testimony improperly drew legal conclusions and should have been excluded where an expert

"opined that [a party's] actions amounted to extortion," DiBella v. Hopkins, 403 F.3d 102, 121 (2d Cir. 2005), or "provided a definition of deadly physical force" and testified that an officer's use of force was "not justified under the circumstances." Hygh, 961 F.2d at 364 (citation omitted).

Federal Rule of Evidence 704 explains that an "opinion is not objectionable just because it embraces an ultimate issue," but prevents expert witnesses in a criminal case from "stat[ing] an opinion about whether the defendant did or did not have a mental state or condition that constitutes an element of the crime charged or of a defense." Fed. R. Evid. 704. "It is well established that Rule 704(b) disables even an expert from expressly stating the final conclusion or inference as to a defendant's actual mental state at the time of a crime. Such testimony is prohibited because it poses a uniquely heightened danger of intruding on the jury's function." United States v. Haynes, 729 F.3d 178, 196 (2d Cir. 2013) (citation omitted).

In Wexler, 522 F.3d 194, the Second Circuit approved the use of expert testimony in a case in which a physician who practiced as a dermatologist was charged with the illegal distribution of Dilaudid and other controlled substances. The Court of Appeals approved the admission of expert testimony that described whether certain treatments were "within the standard of care" provided by dermatologists for certain medical

conditions. Id. at 203. The court found the testimony relevant and helpful to the jury's determination of whether the defendant had acted in good faith in prescribing the controlled substances. Id. at 204. Adopting a Ninth Circuit statement, the court explained, that "only after assessing the standards to which medical professionals generally hold themselves is it possible to evaluate whether a practitioner's conduct has deviated so far from the 'usual course of professional practice' that his actions become criminal". Id.

Fed. R. Crim. P. 16 "requires a defendant to provide at the Government's request a written summary of all expert testimony he plans to use at trial when the Government has complied with a similar request by the defendant." United States v. Yousef, 327 F.3d 56, 148 (2d Cir. 2003). As set forth in Rule 16, the written summary "must describe the witness's opinions, the bases and reasons for those opinions, and the witness's qualifications." Fed. R. Crim. P. 16(b)(1)(C). "The purpose of the expert disclosure requirement is to minimize surprise that often results from unexpected expert testimony, reduce the need for continuances, and to provide the opponent with a fair opportunity to test the merit of the expert's testimony through focused cross-examination." United States v. Ulbricht, 858 F.3d 71, 114 (2d Cir. 2017), cert. denied, 138 S. Ct. 2708 (2018) (citation omitted). Disclosures that merely list general topics

are inadequate. Id. at 115. The disclosure must summarize "the experts' opinions about those topics" and "describe the bases for the experts' opinions." Id.

The Government's Motion to Preclude Certain Expert Testimony

The trial began on February 11. Before jury selection on February 11, the Court ruled on the Government's February 7 motion to preclude portions of Dr. Warfield's testimony. Among other things, the Court explained the legal standard that the Government would have to meet to convict a physician of the illegal distribution of controlled substances and the standard that governs expert testimony generally and in a case with such a charge.

The Court began by observing that it was unclear whether Dr. Warfield was disputing Dr. Waldman's very concrete and detailed testimony about the standard of medical care for pain management, including, for instance, the standard of care for initial or for follow-up visits, the kinds of patient complaints for which fentanyl and oxycodone are appropriate, the dosage regimens for these drugs, and alternative treatments that should be explored before opioids are considered or prescribed. Defense counsel assured the Court that Dr. Warfield did disagree with Dr. Waldman and offered to provide a supplemental report. Dr. Waldman was expected to testify on February 14, and the

Court ordered that the supplemental report would be due by February 12 at noon.

Although the February 7 Disclosure had not included a description of the standard of care for physicians practicing pain management, the Court ruled that if the defendant wished, Dr. Warfield would be permitted to include one in the supplemental disclosure and then to testify about that standard if she did. Similarly, the supplemental disclosure could describe the role of the eight factors listed in the February 7 Disclosure in the treatment of pain, and the standards for prescribing oxycodone and fentanyl to treat pain. The Court also ruled that Dr. Warfield could testify, based on her review of identified patient records, as to whether those records reflect that Lopez prescribed opioids in the usual course of professional practice.

The Court found that the majority of the testimony described in the February 7 Disclosure was improper and could not be presented. It ruled that Dr. Warfield would not be permitted to testify in a way that would intrude on the Court's obligation to describe the legal standard for the jury, or on the jury's duty to be the sole and exclusive fact finder. The Court also ruled that Dr. Warfield was precluded from presenting any testimony suggesting that defendant Lopez could not be found guilty because there are no regulations or standards dictating

the precise criteria for prescribing oxycodone and fentanyl. A physician's duty to prescribe controlled substances in the usual course of professional practice has been clear since at least 1975. See United States v. Moore, 423 U.S. 122 (1975). The proposed discussion by Dr. Warfield about the existence or nonexistence of regulations would essentially be a request that the jury find the defendant not guilty because the law is too imprecise, which is both an inaccurate statement of the law and would usurp the Court's role in charging the jury as to the law.

For the same reason, Dr. Warfield was also precluded from providing definitions for and comparing the terms "standard of care" and the "usual course of professional practice" and from discussing what standards do or do not apply in civil litigation. She was permitted, however, to explain, if included in a supplemental Rule 16 disclosure, what constituted, during the relevant time, the standard of care for specialists treating pain, including in the prescribing of oxycodone and fentanyl.

Dr. Warfield provided a supplemental Rule 16 disclosure on February 12, which the parties agreed would replace the February 7 disclosure (the "February 12 Disclosure"). The February 12 Disclosure did not include a description of the standard of care for pain management or for the prescribing of oxycodone or fentanyl. The February 12 Disclosure did, however, identify twenty-two statements in Dr. Waldman's proposed testimony with

which Dr. Warfield disagreed. For example, the February 12 Disclosure explained that she disagreed that a physician forms a diagnosis of a patient by physically examining him, talking to him, ordering diagnostic tests, and then developing a treatment plan that typically incorporates physical therapy, injections, muscle relaxants, nerve pain medication, and, sometimes, opioids. According to Dr. Warfield, diagnostic testing may or may not be ordered by a pain doctor forming a diagnosis plan for a patient and there is no typical treatment plan for pain. Rather, a variety of approaches can be appropriate ways for a doctor to treat pain. The Government did not object to the February 12 Disclosure.

Objections to Dr. Warfield's Testimony at Trial

The defendant called Dr. Warfield to testify on February 19. The Government objected to many defense questions as beyond the scope of the February 12 Disclosure. During a conference with counsel, the Court directed defense counsel to restrict the questioning to the February 12 Disclosure. The Court gave counsel an opportunity to confer regarding any testimony that was not part of the February 12 Disclosure. The Court also suggested that defense counsel might be able to elicit the testimony that they desired to present in the context of discussing the identified patient files and the eight factors listed in their two disclosures of Dr. Warfield's testimony.

Subsequently, when uncertain whether the February 12 Disclosure had given notice of the testimony, the Court asked defense counsel to direct the Court to the pertinent paragraph. Where counsel could do so, the objection was overruled.

Dr. Warfield was able to testify without objection about many aspects of the standard of care that pain management doctors typically follow. She described the different types of pain clinics in the United States, from those in an academic setting to those operated by a single practitioner. She described a range of medications that can be used to treat pain. She discussed the appropriate dosage for opioids and the types of pain for which fentanyl and oxycodone are prescribed. She described the risks of taking oxycodone and when it may be appropriate to prescribe oxycodone to patients addicted to the drug. She opined that a patient who is diverting pills may fool his or her doctor. She testified that the type of physical examination performed by a pain management doctor during an initial visit would "very much depend[] on the patient's complaint, and . . . on the physician's experience and what the physician is looking for" and that it is "left up to the individual physician as to what maneuvers they feel are appropriate" in an initial physical exam. She also described what should be done on a follow-up visit. She explained how to interpret a patient's response to a pain scale. She explained

the relationship between an MRI and a patient's perceived pain level. Dr. Warfield testified that when a patient's urine drug test comes up positive for an illicit substance, the treating physician could reasonably decide to discontinue the patient's opioid prescription, or to continue the patient's opioid treatment and give the patient another chance or even several more chances. Dr. Warfield then discussed in detail specific patient files and undercover videos of visits with Lopez, commenting on what she found to be appropriate care that she would expect of a doctor. In reviewing patient files showing that Dr. Lopez continued to prescribe oxycodone to returning patients despite their urine tests showing no trace of oxycodone, she testified that "it may be perfectly reasonable to continue the medication as Dr. Lopez did." Dr. Warfield also was able to testify without objection, based on her review of patient records and video recordings of patient visits, that Lopez was "acting within the usual course of medical practice in treating those patients."

Conclusion

Dr. Warfield's testimony was limited at trial by the scope of the defense disclosures made pursuant to Rule 16, Fed. R. Crim. P., and by the standards that govern expert testimony.

She was not permitted to compare legal standards that apply in civil and criminal cases or to define legal standards.

Dated: New York, New York
April 11, 2019

DENISE COTE
United States District Judge